UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
ALAN HURLEY, an individual; Plaintiff, vs. AUXILIUM PHARMACEUTICALS, INC. and DPT LABORATORIES, Ltd., Defendants.	COMPLAINT AND JURY DEMAND Civil Action No.: _____

COMPLAINT

The Plaintiff, Alan Hurley, states and brings this civil action before the Court for the United States District Court for the Northern District of Illinois as a related action in the matter entitled In Re: Testosterone Replacement Therapy Products Liability Litigation, MDL No. 2545.

The Plaintiff, Alan Hurley, is a competent individual, complaining against Defendants, Auxilium Pharmaceutical, Inc. and DPT Laboratories, Ltd., and states as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. INTRODUCTION

1. This case involves the prescription Testim which is manufactured, sold, distributed and promoted by the Defendants, Auxilium, Inc. and DPT Laboratories, Ltd. (hereinafter jointly "the Defendants" or "Auxilium"), as a testosterone replacement therapy.

2. The Defendants misrepresented that Testim was a safe and effective treatment for hypogonadism and a condition they referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. Testim is an exogenous form of the androgen testosterone. It regulates the expression of platelet TXA_2 receptors in humans which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

4. Testim is a hydro-alcoholic gel containing testosterone, and is applied to upper arms and shoulders. Testim enters the body through transdermal absorption. The FDA approved Testim on October 31, 2002. Testim was widely advertised and marketed as a safe and effective testosterone replacement therapy.

5. The Defendants failed to adequately warn physicians about the risks associated with Testim and the monitoring required to ensure their patients' safety.

6. The Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for Testim. Further, the Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "Low T," an abbreviated term for low testosterone.

7. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

8. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "Low T." Additionally, low testosterone is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

9. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially.

10. Consumers of Testim and their physicians relied on the companies' false representations and were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

B. PARTIES

11. At the time the Plaintiff used Testim and was injuries, the Plaintiff, Alan Hurley was a resident of the state of New York.

12. Upon information and belief, the Defendant, Auxilium Pharmaceuticals, Inc., the manufacturer of Testim, is a corporation organized and existing under laws of Delaware with its principal place of business at 640 Lee Road, Chesterbrook, Chester County, Pennsylvania 19087. Although this Complaint is being filed in an MDL proceeding pursuant to a Direct Filing Order, the Plaintiff avers in an abundance of caution that the Defendant, Auxilium Pharmaceuticals, Inc., has conducted business and derived substantial revenue from within the State of New York.

13. The Defendants engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, selling and introducing into the stream of commerce products known as Testim. The Defendants sold and marketed Testim in New York and throughout the United States.

14. The officers and directors of the Defendants participated in, authorized, and directed the production and promotion of Testim when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by the Plaintiff herein.

15. The Defendant, DPT Laboratories, Ltd., is a limited partnership existing under the laws of Texas with its primary place of business at 318 McCullough Ave., Ocean County, San Antonio, Texas 78215. Although this Complaint is being filed in an MDL proceeding pursuant to a Direct Filing Order, the Plaintiff further avers in an abundance of

caution that the Defendant, DPT Laboratories, Ltd., has conducted business and derived substantial revenue from within the State of New York.

16. The Defendant, DPT Laboratories, Ltd., engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, selling and introducing into the stream of commerce products known as Testim. The Defendant, DPT Laboratories, Ltd. sold and marketed Testim in New York and throughout the United States.

17. The officers and directors of the DPT Laboratories, Ltd. participated in, authorized, and directed the production and promotion of Testim when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by the Plaintiff herein.

C. JURISDICTION AND VENUE

18. This Court has jurisdiction over the Defendants and this action pursuant to 28 U.S.C § 1332 because there is complete diversity of citizenship between the Defendants and the Plaintiff and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

19. This Court has personal jurisdiction over the Defendants pursuant to this Court's Case Management Order #12, dated October 24, 2014, permitting direct filing in this Court for consideration for transfer into MDL No. 2545. The United States District Court for the Eastern District of New York also has personal jurisdiction over the Defendants because the Defendants transact business in Watkins Glen, New York and the wrongs complained of arose in Watkins Glen, New York.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and also

under this Court's Case Management Order #12, dated October 24, 2014, permitting direct filing in this Court for consideration for transfer into MDL No. 2545.

21. Venue in this case is also appropriate in the Eastern District of New York pursuant to 28 U.S.C. § 1391 because Plaintiff was prescribed Testim, purchased and used Testim, and suffered injuries from Testim in Watkins Glen, New York, and because the Defendants transact business in Watkins Glen, New York.

22. The Plaintiff states that but for the Order permitting direct filing into the Northern District of Illinois pursuant to Case Management Order No. 12, Plaintiff would have filed in the United States District Court for the Eastern District of New York. Therefore, the Plaintiff respectfully requests that at the time of the transfer of this action back to the trial court for further proceedings, if any, that this case be transferred to the above referenced District Court.

23. The Plaintiff, Alan Hurley, is a resident and citizen of Watkins Glen, New York and claims damages as set forth below.

D. FACTUAL BACKGROUND

1. General Allegations

24. This action is for damages brought on behalf of the Plaintiff who was prescribed and supplied with, received, and who has taken the prescription drug, Testim, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by the Defendants. This action seeks, among other relief, special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by these drugs.

25. The Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused the Plaintiff's and Plaintiff's injuries and damages.

26. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug, Testim, for the use and application by men, including, but not limited to, the Plaintiff.

27. At all times herein mentioned, the Defendants were authorized to do business within the state of New York.

28. At all times herein mentioned, the officers and directors of the Defendants participated in, authorized, and directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by the Plaintiff herein.

29. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff, could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, Plaintiff had been injured, the cause of the injuries, or tortious nature of the conduct causing injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical

profession that the drug Testim is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Regulatory History and Approved Uses

30. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

31. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

32. In men, testosterone levels normally begin a gradual decline after the age of thirty.

33. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

34. Testim is a hydroalcoholic gel containing testosterone, and it is applied to the upper arms and shoulders. The FDA approved Testim on October 31, 2002 for the treatment of adult males who have low or no testosterone (a condition called hypogonadism) in conjunction with an associated medical condition. After FDA approval, Testim was widely advertised and marketed by the Auxilium and DPT Laboratories, Ltd. as a safe and effective testosterone replacement therapy.

35. Hypogonadism is a specific and recognized condition of the endocrine

system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders and other conditions which cause suppression of gonadotropin-releasing hormone (GnRH).

36. At all times material hereto, and since the time that Testim first received approval from the FDA, the Defendants knew and understood the FDA-approved indications for clinical use of Testim.

3. Direct to Consumer Marketing and Promotion to Physicians for Unbranded/Off-Label Use.

37. The Defendants expanded the indications for use by promoting and detailing "Low T" as an acquired form of hypogonadism, and advantaged intentional ambiguity in the Testim product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

38. The Defendants coordinated massive advertising campaigns targeted toward men who did not have Hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. The direct-to-consumer marketing was designed to convince men that they suffered from a non-existent and unrecognized medical condition called "Low T," which was a term for low testosterone. The Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaigns consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Testim users, and online media.

39. The Defendants' advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

40. Since the FDA approved Testim for a very specific medical condition called Hypogonadism, the Defendants have also sought to convince primary care physicians that Hypogonadism is synonymous with "Low T" and that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

41. While running their disease awareness campaigns, the Defendants promote their products as easy-to-use topical testosterone replacement therapies.

42. The Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on the Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

43. The Defendants manufactured, sold and promoted the drug to treat a non-existent medical condition that they called "Low T," which was a name they created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, the Defendants marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

44. The Defendants successfully created a robust and previously nonexistent market for their drugs.

45. As observed by Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. in their article "Low T as a Template: How to Sell Disease" published in JAMA Internal Medicine 173(15):1460-1462 (August 12/26, 2013) concerning the "Low T" campaigns by the pharmaceutical industry:

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

46. The Defendants' advertising paid off. Sales of replacement therapies have more than doubled since 2006 and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

47. The Defendants engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T."

48. The marketing programs sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a

large number of men in the United States, and that the use of Testim was safe for human use as a treatment for "Low T," even though the Defendants knew these representations to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

49. At all times material hereto, the Defendants' marketing strategy included the use of sales or drug detailing representatives ["reps"] and marketing and brand team personnel who performed on-line and in-person Testim product-detailing to physicians, and promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

50. The Defendants' drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of Testim products, as well as discount and/or rebate coupons to give to patients for the purchase of Testim.

51. The Defendants' drug "reps" detailed and marketed Testim to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

52. The Defendants denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

53. The Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

54. The Defendants knew and understood the FDA regulations pertaining to "off- label" marketing and promotion of an FDA-approved pharmaceutical product.

55. The Defendants marketed, promoted, and detailed Testim for "off-label" use for the purpose of "label expansion," and detailed and promoted the products to physicians, and advertised the products to consumers and patients, under the rubric that "Low T" was an indication for clinical use of Testim products.

56. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

57. A manufacturer misbrands a drug if the labeling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

58. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

59. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

60. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

61. The FDA did not, and never has, approved Testim for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or,

g. bone strength or density abnormalities.

4. Adverse Events and Serious Health Risks Caused by TRT.

62. There have been a number of studies associating testosterone use in men with an increased risk of serious injuries from blood clots, cerebrovascular injuries and cardiovascular injuries.

63. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

64. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[1] and serum estradiol levels[2]. It can also cause increased platelet aggregation and vasoconstriction.

65. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

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[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.

[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

66. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

67. The clinical trial data submitted to the FDA for the approval of AndroGel showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

68. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

69. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than

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[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

[4] Wannamethee G1, Perry IJ, Shaper AG, Haematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

or equal to 50% had almost double the risk of new-onset heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

70. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

71. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

72. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[8] An increase in blood viscosity is a known risk factor for ischemic heart disease[9], and it can cause

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[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011.

[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic

hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

73. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

74. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

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heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.

[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.

75. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

76. In a study published 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis in men.

77. In a case control study of men in the Framingham cohort *supra*, serum estradiol levels were significantly increased in subjects with coronary heart disease.[15]

78. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of

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[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.

[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.

the heart in males with elevated levels of serum estradiol. [16] Impaired contractile function results in numerous cardiovascular injuries and disease.

79. A study published in 2007 compared blood levels of testosterone and *estradiol* in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of *estradiol* in both groups of heart attack patients compared with those without coronary disease.[17] In another study, men admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients, *estradiol* levels in these heart attack patients were **180%** higher, while bioavailable testosterone levels were **nearly three times less** than those of control patients.[18]

80. High testosterone levels enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after MI, and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.[19]

81. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2has

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[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

[17] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.

[18] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.

[19] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory PhysiologyPublished 1 May 2006**Vol.** 290**no.** H2043-H2050**DOI:** 10.1152/ajpheart.01121.2005

been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[20]

82. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

83. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels", in which a large cohort of men who used testosterone taken from a database of the Veteran's Administration was compared against a cohort of men who did not use testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

84. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

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[20] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

85. In a study published in 2013[21], based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy among men lasting 12+ weeks reporting cardiovascular-related events, two reviewers independently searched, selected and assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

86. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

5. Inadequate Warnings and Labeling

87. The Defendants' marketing strategy has been to aggressively market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of hypogonadism/low testosterone and by failing to protect users from serious dangers that the Defendants knew or should have known to result from use of their products.

88. The Defendants successfully marketed Testim by undertaking "disease awareness" marketing campaigns. These campaigns sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with

[21] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

89. The Defendants' advertising programs sought to create the image and belief by consumers that the use of Testim was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though the Defendants knew or should have known this to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

90. The Defendants promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. The Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

91. The Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Testim. The Defendants deceived potential Testim users and their physicians by relaying positive information through the press and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

92. The Defendants concealed material relevant information from potential Testim users and their physicians, and they minimized user and prescriber concern regarding the safety of Testim, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

93. In particular, in the warnings the Defendants gave (prior to Mr. Hurley's heart

attack) in their commercials, online and print advertisements, the Defendants failed to mention any potential risk of cardiac event, stroke, TIA, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represented that the Defendants adequately tested Testim for all likely side effects. The Defendants also failed to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

94. Testim's prescribing information at the time of Mr. Hurley's heart attack did not warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

95. The warnings in Testim's prescribing information consist of:

- Monitor patients with benign prostatic hyperplasia (BPH) for worsening signs and symptoms of BPH.
- Avoid unintentional exposure of women and children to Testim. Secondary exposure to testosterone can produce signs of virilization. Testim should be discontinued until the cause of virilization is identified.
- Exogenous administration of androgens may lead to azoospermia.
- Edema, with or without congestive heart failure, may be a complication in patients with preexisting cardiac, renal, or hepatic disease.

However, the Defendants' prescribing information fails to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. They also fail to instruct patients or physicians to be aware of the presence of comorbid conditions or pre-existing heart disease,

which has been proven to double the risk in men under the age of 65 who use testosterone therapy.

96. The Defendants' prescribing information does not instruct physicians or patients that Testim can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count does not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor does it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%, including the fact that individuals with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

97. The Defendants' prescribing information does instruct physicians to check their patient's hematocrit and hemoglobin levels periodically, but it fails to warn patients and their physicians that the product can cause dangerous increases in hematocrit much more rapidly, and also fail to instruct physicians to monitor their patient's hematocrit more frequently.

98. The Defendants' prescribing information fails to state that testosterone replacement therapy should not be administered to men who have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant because the increase in serum estradiol caused by the drug can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones. It also fails to instruct physicians to screen all patients for underlying clotting traits before prescribing testosterone replacement therapy.

99. The Defendants' prescribing information and medication guides contained within

their package materials fail to warn that use of the product may result in elevated levels of estradiol. They do not instruct physicians to monitor estradiol levels, nor do they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There is also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

100. The Defendants' prescribing information at the time of Mr. Hurley's heart attacks did not warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, TIA, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

101. The Defendants' prescribing information and medication guides contained within the package materials do not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There is no mention of the fact that there is a doubling of the risk of heart attacks in men over the age of 65 who use testosterone replacement therapy, despite the fact that the data supporting this finding has been available for years. The Defendants have no warning about the increased risk of heart attack in men younger than 65 with a prior history of heart disease. The Testim label only warns that there is insufficient long-term safety data in geriatric patients to assess the potentially increased risks of cardiovascular disease and prostate cancer. This absence of a warning fails to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

102. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, et al. published as article in the Journal of the American Medical Association entitled Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels ["Vigen Paper"].

103. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

104. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, et al. published an article in PLOS ONE entitled Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men ["Finkle Paper"].

105. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

106. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the United States Food & Drug Administration (FDA) announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

107. As a result of this mandate by the FDA, on June 21, 2014, the Defendants updated the prescribing information to provide the general warning required by FDA regarding DVT and PE. The Defendants' new warning is as follows:

There have been postmarketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as Testim. Evaluate patients who report symptoms of pain, edema, warmth and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a venous thromboembolic even is suspected, discontinue use with Testim and initiate appropriate workup and management.

108. However, and in any event, these warnings still lack warning about the risks of elevated estradiol levels, and the need to screen for underlying clotting traits; also they contain no warnings for strokes or for cardiovascular injuries.

109. The marketing and promotion of these testosterone products to patients and physicians overstated their benefits by creating the impression that they were a safe and effective

treatment for a variety of aging-related conditions and symptoms, for which they were not FDA-approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of this drug.

110. As a result of Defendants' advertising, marketing, and representations about their products, men in the United States pervasively seek out prescriptions for Testim. If the Plaintiff and his physician had known the risks and dangers associated with Testim, the physician would not have prescribed nor would the Plaintiff have used Testim and consequently would not have been subject to its serious side effects; and/or, the Plaintiff's physicians would have adequately monitored the Plaintiff's hematocrit and estradiol levels, and, as a result, the Plaintiff's injuries would have not otherwise have occurred.

6. Case Specific Facts

111. The Plaintiff is 51 years old. He lives in Watkins Glen, New York.

112. The Plaintiff sought specific testing and treatment for "Low T" based upon the representations and medical information provided to him and/or his physician by the Defendants through direct-to-consumer educational and information "Low T" awareness campaigns propagated by the Defendants.

113. The Defendants sought to raise the awareness of physicians, including Alan Hurley's physician, with respect to a condition denominated as hypogonadism/"Low T," and to educate physicians about hypogonadism/"Low T" and its treatment.

114. The Defendants had a duty to warn prescribing physicians about the risks of Testim use, including the risks of heart attacks.

115. The Plaintiff's physician would not have prescribed Testim to his patient had he been advised of and warned of the risks of cardiovascular and/or cerebrovascular injuries caused

by or increased with respect to the risk of harm by Testim.

116. The Plaintiff commenced treatment with Testim in or around 2011 after being prescribed this medication by his physician. Thereafter, Plaintiff continued on using Testim until the date of his heart attack.

117. On or about December 19, 2011, the Plaintiff began to experience an acute onset of chest pain.

118. On or about December 19, 2011, the Plaintiff went to Schuyler Hospital.

119. On or about December 19, 2011, the Plaintiff was transferred to Robert Packer Hospital.

120. In June of 2014, Plaintiff saw a television commercial about testosterone causing thromboembolic events, heart attacks and strokes.

121. Prior to June 2014, Plaintiff was unaware of any connection between the use of Testim and the Plaintiff's heart attack.

122. The Plaintiff's injuries were directly and proximately caused by his use of Testim by the mechanism of injury as described above.

123. There was no warning to the Plaintiff, his physician, or Plaintiff that Testim presented a severe risk of a heart attack.

124. Had the Plaintiff and his physicians known the true risks associated with the use Testim, he would not have used the Testim and/or would have been adequately monitored for its side effects, and as a result, he would not have incurred the injuries or damages he did as a result of his use of Testim.

125. Because of the Defendants' aforesaid actions, the Plaintiff suffered a heart attack and suffered expenses for medical treatment and hospitalization, as well as any and all

damages that are reasonable in the premises.

II. CAUSES OF ACTION

Count One – Design Defect

126. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

127. The Defendants participated in the manufacture, sale and marketing of exogenous testosterone drugs that were FDA-approved to treat a specific medical condition called Hypogonadism, which is defined as a condition in which a male produces no or very low testosterone in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

128. The Defendants manufactured, sold, and promoted Testim which contained a defective condition because the design was defective and unsafe in that it caused serious injuries and death as the result of the formation of blood clots and adverse cerebrovascular/cardiovascular injuries, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

129. That Testim was unreasonably dangerous in design in that, at the time when Testim left the Defendants' control, there existed alternative designs for the product that were capable of preventing the Plaintiff's damages; and the likelihood that the design of Testim would cause the Plaintiff's injuries and damages and the gravity of those injuries and damages outweighed the burden on the manufacturers of adopting such alternative designs and the adverse effect, if any, of such alternative designs on the utility of the product.

130. These design defects made the drug unreasonably dangerous, yet the Defendants knowingly introduced the drug into the market.

131. The drug, as manufactured by the Defendants, remained unchanged and was in the same condition at the time of the injury hereafter alleged.

132. As a result of the foregoing, the Plaintiff was caused to suffer a fatal heart attack, as well as expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

Count Two – Negligence

133. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

134. At all times herein mentioned, the Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Testim.

135. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of Testim to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular injuries, deep vein thrombosis and it sequelae, pulmonary embolism, and sudden cardiovascular death.

136. The Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of Testim to heart attack, stroke, TIA, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

137. The Defendants' duty of care owed to consumers and patients included providing accurate, true, and correct information concerning hypogonadism/"Low T" and its diagnostic criteria, the FDA-approved indications for the clinical use of Testim products, the clinical safety and effectiveness profiles of Testim, and, appropriate, complete, and accurate warnings concerning the adverse effects of Testim, including heart attack, stroke, TIA, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

138. At all times herein mentioned, the Defendants breached their duty of care by negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use and selling Testim, and the Defendants failed to adequately test and warn of the risks and dangers of Testim as described herein.

139. Despite the fact that the Defendants knew or should have known that Testim caused unreasonable, dangerous side effects, the Defendants continued to market Testim to consumers including the Plaintiff, when there were safer alternative methods.

140. The Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular injuries causally associated with Testim use.

141. As marketed, detailed, and promoted to physicians, including the Plaintiff's prescribing physician, the Defendants failed to warn that Testim caused, or increased the risk of harm of, cardiovascular and cerebrovascular injuries, including myocardial infarction, pulmonary embolism, TIA, deep vein thrombosis and its sequelae, and sudden cardiac death.

142. The Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

143. As a direct and proximate cause of the Defendants' aforesaid actions and of the Plaintiff reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by the Defendants, the Plaintiff suffered serious personal injuries, which are permanent in nature, including but not limited to past, present and future pain and suffering, expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

144. Testim's breach of the duty to warn caused or increased the risk of harm of the Plaintiff's injuries.

Count Three – Strict Products Liability – Failure to Warn

145. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

146. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

147. The Plaintiff's use of Testim was a reasonably anticipated use of this product.

148. The Testim manufactured and/or supplied by the Defendants was defective due to inadequate warnings or instructions because the Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

149. The Defendants failed to adequately warn consumers, such as the Plaintiff and/or his health care providers, that Testim could cause heart attacks, strokes, TIA pulmonary embolism, cardiovascular injuries and blood clots.

150. The Defendants failed to adequately warn consumers and/or their health care

providers that while a patient was using Testim, it was necessary to frequently monitor hematocrit and/or estradiol levels to prevent heart attacks, strokes, TIAs, pulmonary embolisms, cardiovascular events and blood clots.

151. The Testim manufactured and/or supplied by the Defendants was defective due to inadequate post-marketing warnings or instructions because, after the Defendants knew or should have known of the risk of serious bodily harm from the use of Testim, the Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

152. As a direct and proximate cause of the Defendants' aforesaid actions and of the Plaintiff's reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by the Defendants, the Plaintiff suffered serious personal injuries, which are permanent in nature, including but not limited to expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

Count Four – Breach of Implied Warranty

153. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

154. Prior to the time that the aforementioned product was used by the Plaintiff, the Defendants impliedly warranted to the Plaintiff and the Plaintiff's agents and physicians that Testim was of merchantable quality and safe and fit for the use for which it were intended.

155. Specifically, the Defendants warranted to the Plaintiff that their product Testim was intended to treat a condition called hypogonadism/"Low T" and that it was safe and fit for

that use.

156. The Plaintiff was unskilled in the research, design and manufacture of medical drugs, including Testim, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Testim. As a result, the Plaintiff used the Defendants' product as it was warranted and used it as intended.

157. Testim was neither safe for its intended use nor of merchantable quality, as warranted by the Defendants, in that Testim has dangerous propensities when used as intended and will cause severe injuries to users.

158. As a direct and proximate cause of the Defendants' aforesaid actions and of the Plaintiff's reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by the Defendants, the Plaintiff suffered serious personal injuries, which are permanent in nature, including but not limited to past, present and future pain and suffering, expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

Count Five - Breach of Express Warranty

159. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

160. At all times mentioned, the Defendants expressly represented and warranted to the Plaintiff agents and physicians, by and through statements made by the Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Testim was FDA-approved to treat a condition called hypogonadism/"Low T," and that it was

safe, effective, fit and proper for its intended uses. The Plaintiff purchased Testim relying upon these warranties.

161. In utilizing Testim, the Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of the Defendants. These warranties and representations were false in that Testim is unsafe and unfit for its purported intended uses and the use of Testim can cause severe injuries, such as the Plaintiff 's heart attack.

162. As a direct and proximate cause of the Defendants' aforesaid actions and of the Plaintiff's reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by the Defendants, the Plaintiff suffered serious personal injuries, which are permanent in nature, including but not limited to past, present and future pain and suffering, expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

Count Six - Fraud

163. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

164. The Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Testim, and up to the present, knew that their products more than doubled the risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of their products could result in a dramatic increase in serum estradiol levels, yet the Defendants willfully deceived the Plaintiff by concealing from them, his physicians and the general public, the true facts concerning Testim, which the Defendants had a duty to

disclose.

165. At all times herein mentioned, the Defendants conducted a sales and marketing campaign to promote the sale of Testim and willfully deceived the Plaintiff , the Plaintiff's physicians and the general public as to the benefits, regarding the health risks and consequences of using Testim. The Defendants knew of the foregoing, that Testim was not safe, fit and effective for human consumption, that using Testim is hazardous to health, and that Testim has serious propensities to cause serious injuries to its users, including but not limited to the injuries the Plaintiff suffered.

166. The Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that they provided to consumers and patients through their multi-platform marketing, promotional, educational, and awareness campaigns concerning the Testim product and its indications for clinical use; and further knew that consumers and patients would make treatment choices and exercise treatment options about their use of the Testim product in reliance upon this information.

167. Consumers, including Alan Hurley, required, and should have been provided with, truthful, accurate, and correct information concerning the FDA-approved indications for the clinical use for Testim and the clinical safety and effectiveness profiles for Testim, including information concerning the serious injuries such as heart attacks and strokes caused by Testim.

168. The Plaintiff relied on the fraudulent and deceptive representations made by the Defendants to his detriment. Specifically, the Plaintiff relied on representations that Testim was FDA-approved to treat a condition called "LowT/hypogonadism," and that the Defendants' testosterone drug was safe and effective treatment for his "LowT/hypogonadism."

169. The Defendants, from the time they first tested, studied, researched, evaluated,

endorsed, manufactured, marketed and distributed Testim, and up to the present, knew that their products could cause an increase in hematocrit in patients to a level that more than doubles their risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of their products could result in a dramatic increase in serum estradiol levels, yet the Defendants willfully deceived the Plaintiff by concealing from him, the Plaintiff's physicians and the general public, the true facts concerning Testim, which the Defendants had a duty to disclose.

170. At all times herein mentioned, the Defendants conducted sales and marketing campaigns to promote the sale of Testim and willfully deceive the Plaintiff, the Plaintiff 's physicians and the general public as to the benefits, health risks and consequences of using Testim. The Defendants knew of the foregoing, that Testim is not safe, fit and effective for human consumption, that using Testim is hazardous to health, and that Testim has serious propensities to cause serious injuries to its users, including but not limited to the injuries the Plaintiff suffered.

171. The Plaintiff relied on the fraudulent and deceptive representations made by the Defendants to their detriment. Specifically, the Plaintiff relied on representations that Testim was a safe and effective treatment for his hypogonadism/"LowT."

172. The Plaintiff would not have sought or continued treatment for hypogonadism/"Low T" or administered Testim had he been provided with adequate, true, accurate, and correct information by the Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of Testim.

173. During the detailing, marketing, and promotion to physicians, neither the Defendants nor the co-promoters who were detailing Testim on behalf of the Defendants warned

physicians, including the Plaintiff 's prescribing physician, that Testim caused or increased the risk of harm of cardiovascular and/or cerebrovascular injuries and/or neurologic injuries.

174. The Plaintiff would not have used Testim had the educational and informational materials made available to him by the Defendants, and upon which he relied to his detriment, informed him about the risks of cardiovascular and cerebrovascular injuries with product use.

175. As a direct and proximate cause of the Defendants' aforesaid actions and of the Plaintiff 's reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by the Defendants, the Plaintiff suffered serious personal injuries, which are permanent in nature, including but not limited to past, present and future pain and suffering, expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

Count Seven – Negligent Misrepresentation

176. The Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

177. From the time Testim was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, the Defendants made misrepresentations to the Plaintiff , the Plaintiff 's physicians and the general public, including but not limited to the misrepresentations that Testim was safe, fit, effective, and FDA-approved for human consumption to treat hypogonadism/"Low T." At all times mentioned, the Defendants conducted sales and marketing campaigns to promote the sale of Testim and willfully deceive the Plaintiff , the Plaintiff 's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

178. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by the Defendants, by sales representatives and other authorized agents of the Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

179. The representations by the Defendants were in fact false, in that Testim is not safe, fit and effective for human consumption, using Testim is hazardous to health, and Testim has serious propensities to cause serious injuries to users, including but not limited to the injuries suffered by the Plaintiff.

180. The foregoing representations by the Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Testim.

181. The Plaintiff relied on the misrepresentations made by the Defendants to their detriment. Specifically, the Plaintiff relied on representations that the Defendants' testosterone drug was a safe and effective treatment for his hypogonadism/"Low T".

182. In reliance of the misrepresentations by the Defendants, and each of them, the Plaintiff was induced to purchase and use Testim. If Plaintiff had known of the true facts and the facts concealed by the Defendants, the Plaintiff would not have used Testim. The reliance of the Plaintiff upon the Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

183. As a direct and proximate cause of the Defendants' aforesaid actions and of the Plaintiff's reasonably anticipated use of Testim as manufactured, designed, sold, supplied,

marketed and/or introduced into the stream of commerce by the Defendants, the Plaintiff suffered serious personal injuries, which are permanent in nature, including but not limited to past, present and future pain and suffering, expenses for medical treatment and hospitalization, and any and all damages that are reasonable in the premises.

Punitive Damages Allegations

186. Plaintiff adopts by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

187. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of the Plaintiff and other Testim users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Testim. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

188. Prior to the manufacturing, sale, and distribution of Testim, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including the Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Testim.

189. Despite its knowledge, Defendants, acting through its officers, directors, and

managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Testim and failed to warn the public, including the Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Testim. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution and marketing of Testim knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

190. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of the Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiff prays for judgment against the Defendants, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

A. General damages in a sum in excess of the jurisdictional minimum of the Court;

B. Compensatory damages in excess of the jurisdictional minimum of the Court;

C. Medical, incidental, and hospital expenses, past and future, according to proof at the time of trial;

D. For past and future mental and emotional distress, according to proof;

E. Consequential damages in excess of the jurisdictional minimum of this Court;

F. Attorneys' fees, expenses and costs of this action;

G. For pre-judgment and post-judgment interest as provided by law;

H. For full refund of all purchase costs Plaintiff paid for testosterone;

I. For punitive or exemplary damages according to proof; and

J. For such other and further relief as the Court may deem necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

Date: January 16, 2015

Respectfully Submitted,

Law Offices of Robert W. Jackson, APC

By: /s/ Robert W. Jackson
ROBERT W. JACKSON, ESQUIRE